

This listing of claims will replace all prior versions and listings of claims in the Application.

**Listing of Claims:**

1 to 21. (Canceled)

22. (New) A method of producing a dry powder formulation as an ordered mixture having fine particle fractions of reduced sensitivity to penetrating moisture, for inhalation, comprising

a) a pharmaceutically inactive carrier having particles of noninhalable particle size, and

b) a pharmaceutically active component comprising at least one finely divided pharmaceutically active compound having particles of inhalable size, said method comprising the step of mixing said carrier, said pharmaceutically active component and pulverulent magnesium stearate.

23. (New) The method of Claim 22, comprising mixing by tumble blending.

24. (New) The method of Claim 22, comprising first mixing the carrier with the magnesium stearate and then admixing the pharmaceutically active component therewith.

25. (New) The method of Claim 22, comprising first mixing the carrier with the pharmaceutically active component and then admixing the magnesium stearate therewith.

26. (New) The method of Claim 22, wherein the pharmaceutically active compound is a hygroscopic compound capable of absorbing at least 0.5% by weight of its own weight of absorptively bound water when stored in air having a relative humidity of 50%.

27. (New) The method of Claim 22, wherein the pharmaceutically active compound is a hydrophilic compound having a wetting angle of less than 90°.

28. (New) The method of Claim 22, wherein the pharmaceutically active compound is a hydrophilic compound having a wetting angle of less than 70°.

29. (New) The method of Claim 22, wherein the pharmaceutically active compound is formoterol or a pharmaceutically acceptable salt thereof.

30. (New) The method of Claim 22, wherein the pharmaceutically active compound is selected from the group consisting of formoterol fumarate, formoterol tartrate, ipratropium bromide and tiotropium bromide.

31. (New) The method of Claim 22, wherein the pharmaceutically active

component further comprises a second pharmaceutically active compound having particles of inhalable size.

32. (New) The method of Claim 31, wherein the pharmaceutically active component is selected from the group consisting of

a) formoterol fumarate, formoterol tartrate, levalbuterol sulfate and salmeterol xinafoate, and

b) a corticosteroid.

33. (New) The method of Claim 22, wherein the pharmaceutically active compound has a mean particle size of 1 to 10  $\mu\text{m}$ .

34. (New) The method of Claim 22, wherein the pharmaceutically active compound has a mean particle size of 1 to 6  $\mu\text{m}$ .

35. (New) The method of Claim 22, wherein the magnesium stearate is present in an amount of 0.1 to 2% by weight, based on the total weight of the formulation.

36. (New) The method of Claim 22, wherein the magnesium stearate is present in an amount of 0.25 to 1% by weight, based on the total weight of the formulation.

37. (New) The method of Claim 22, wherein the magnesium stearate is present in an amount of 0.4 to 0.8% by weight, based on the total weight of the formulation.

38. (New) The method of Claim 22, wherein the carrier is selected from the group consisting of monosaccharides, disaccharides, sugar alcohols, polylactic acid and cyclodextrin.

39. (New) The method of Claim 22, wherein the carrier is selected from the group consisting of glucose, lactose monohydrate and trehalose.

40. (New) The method of Claim 22, wherein the carrier particles have a mass mean aerodynamic diameter of 10 to 500  $\mu\text{m}$ .

41. (New) The method of Claim 22, wherein the carrier particles have a mass mean aerodynamic diameter of 50 to 200  $\mu\text{m}$ .

42. (New) The method of Claim 22, further comprising admixing particles of micronized lactose monohydrate wherein at least 50% of the particles thereof have a maximum particle size of 10  $\mu\text{m}$ , with said carrier, said pharmaceutically active component and said magnesium stearate.

43. (New) A method of stabilizing fine particle fractions of dry powder formulations for inhalation against penetrating moisture, comprising

- a) a pharmaceutically inactive carrier, and
- b) a finely divided pharmaceutically active compound,

comprising the step of mixing said carrier having particles of noninhalable particle size, said pharmaceutically active compound having particles of inhalable particle size and pulverulent magnesium stearate, thereby producing an ordered mixture of increased stability to penetrating moisture.

44. (New) A multidose dry powder inhaler, having reduced moisture sensitivity, comprising

a) a powder reservoir containing a dry powder formulation in the form of an ordered mixture, comprising

i) a pharmaceutically inactive carrier having particles of noninhalable particle size,

ii) a pharmaceutically active component comprising at least one finely divided pharmaceutically active compound having particles of inhalable particle size, and

iii) magnesium stearate

and

b) means for delivering metered doses of pharmaceutically active compound for inhalation.

45. (New) The multidose dry powder inhaler of Claim 44, wherein the pharmaceutically active compound is a hygroscopic compound capable of absorbing at least 0.5% by weight of its own weight of absorptively bound water when stored in air having a relative humidity of 50%.

46. (New) The multidose dry powder inhaler of Claim 44, wherein the pharmaceutically active compound is a hydrophilic compound having a wetting angle of less than 90°.

47. (New) The multidose dry powder inhaler of Claim 44, wherein the pharmaceutically active compound is a hydrophilic compound having a wetting angle of less than 70°.

48. (New) The multidose dry powder inhaler of Claim 44, wherein the magnesium stearate is present in an amount of 0.1 to 2% by weight, based on the total weight of the formulation.

49. (New) The multidose dry powder inhaler of Claim 44, wherein the magnesium stearate is present in an amount of 0.25 to 1% by weight, based on the total weight of the formulation.

50. (New) The multidose dry powder inhaler of Claim 44, wherein the magnesium stearate is present in an amount of 0.4 to 0.8% by weight, based on the

total weight of the formulation.

51. (New) The multidose dry powder inhaler of Claim 44, wherein the carrier is selected from the group consisting of monosaccharides, disaccharides, sugar alcohols, polylactic acid and cyclodextrin.

52. (New) The multidose dry powder inhaler of Claim 44, wherein the carrier is selected from the group consisting of glucose, lactose monohydrate and trehalose.

53. (New) The multidose dry powder inhaler of Claim 44, wherein the formulation further comprises particles of micronized lactose monohydrate wherein at least 50% of the particles thereof have a maximum particle size of 10  $\mu\text{m}$ .

54. (New) The multidose dry powder inhaler of Claim 44, wherein the pharmaceutically active compound is formoterol or a pharmaceutically acceptable salt thereof.

55. (New) The multidose dry powder inhaler of Claim 44, wherein the pharmaceutically active compound is selected from the group consisting of formoterol fumarate, formoterol tartrate, ipratropium bromide and tiotropium bromide.

56. (New) The multidose dry powder inhaler of Claim 44, wherein the formulation further comprises a second pharmaceutically active compound having

particles of inhalable size.

57. (New) The multidose dry powder inhaler of Claim 44, wherein the pharmaceutically active component comprises

- a) a member selected from the group consisting of formoterol fumarate, formoterol tartrate, levalbuterol sulfate and salmeterol xinafoate, and
- b) a corticosteroid.

58. (New) A dry powder formulation for inhalation in the form of an ordered mixture, comprising

- a) a pharmaceutically inactive carrier having particles of noninhalable particle size,
- b) at least two finely divided pharmaceutically active compounds having particles of inhalable particle size, and
- c) magnesium stearate adhering to said particles of said pharmaceutically inactive carrier, the magnesium stearate being in an amount of 0.1 to 2% by weight, based on the total weight of the formulation, said amount being sufficient to provide the formulation with an improved resistance to moisture.

59. (New) The formulation of Claim 58, wherein an at least first pharmaceutically active compound is selected from the group consisting of formoterol fumarate, formoterol tartrate, levalbuterol sulfate and salmeterol xinafoate, and an at least second pharmaceutically active compound is a corticosteroid.



60. (New) The formulation of Claim 59, wherein the magnesium stearate is present in an amount of 0.25 to 1% by weight, based on the total weight of the formulation.

61. (New) The formulation of Claim 58, further comprising particles of micronized lactose monohydrate wherein at least 50% of the particles thereof have a maximum particle size of 10  $\mu\text{m}$ .